In A Game Change, FDA Shifts Criteria for Drug Development to Early-Stage Alzheimer’s Disease

BY MARY BETH NIERENGARTEN

In a move that several leading Alzheimer’s disease (AD) experts welcomed, the Food and Drug Administration (FDA) issued a new guidance document in February refocusing drug development and treatment for Alzheimer’s disease to earlier stages of disease. Among its policy changes, the FDA proposed loosening regulations requiring patients to have both cognitive and functional impairment to be eligible for clinical trials.

The proposed changes, which were explained further in a Mar. 13 paper in the New England Journal of Medicine, reflect an emerging consensus among AD clinicians and investigators that treating patients with primary progressive multiple sclerosis (PPMS) tend to experience more cognitive impairment than patients with relapsing-remitting MS (RRMS), according to a study that involved extensive neuropsychological testing of participants. The study sheds new light in particular on the cognitive profile of PPMS, a disease that MS experts say has been hard to characterize.

“Although PPMS is mainly characterized clinically by spinal cord involvement, we observed that cognitive functions are frequently impaired,” Bruno Brochet, MD, a study coauthor told Neurology Today. “Cognitive impairment appears to be more frequent and severe and concerns a wider range of cognitive functions than in relapsing-remitting MS.”

The study, published online Mar. 20 ahead of the print edition of Neurology, was conducted at the University of Bordeaux in France, where Dr. Brochet is a professor of neurology.

Sequestration Means Fewer Medicare Reimbursement Dollars for Neurologists: How to Lessen the Blow

BY SUSAN KREIMER

Each year in her solo neurology practice, Elaine C. Jones, MD, experiences a surge in overhead costs amid a decline in Medicare reimbursement rates. She expects to feel the pinch even more in 2013.

“It is going to be a big hit,” said Dr. Jones of Southern New England Neurology in Bristol, RI. “The bulk of my patients are certainly Medicare patients.”

Automatic across-the-board spending cuts, known as sequestration, have taken hold. Bipartisan majorities in both the Senate and House included the automatic cuts in the Budget Control Act of 2011 as a strategy to force Congress to act on further deficit reduction. When Congress failed to agree on terms in January, hamstrung mainly

COGNITIVE IMPAIRMENT MAY VARY DEPENDING ON THE TYPE OF MS

BY SUSAN FITZGERALD

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around revenue from tax increases, the automatic spending cuts kicked in for everything from defense spending to Head Start. Starting on April 1, physicians, hospitals, and other providers began seeing a 2-percent reduction in payments from the Centers for Medicare & Medicaid Services (CMS). This — coming on the heels of an overall 7-percent decrease in CMS reimbursement for neurology, including severe

cuts to electromyography and nerve conduction studies as of Jan. 1 — has neurologists openly questioning the viability and future of the specialty. [At the AAN annual meeting, a one-hour Hot Topics session, Neurology in Crisis, went 60-minutes over its time-allocation to give voice to the growing frustration around the financial blows to the specialty.] Practices will incur up to a 53- to 66-percent reduction in reimbursement for certain nerve conduction codes, as delineated by the reassigned relative value units (RVUs). [Neurology Today has covered this issue in a series of stories — the latest, in February. http://bit.ly/YIPkJ3 ]

One-quarter of Dr. Jones’ practice involves nerve conduction studies. The reimbursement for some codes was slashed more than for others, and “it worked out that the more complicated the procedure, the bigger the cut,” said Dr. Jones, chair of the AAN Government Relations Committee.

Psychogenic Nonepileptic Seizures
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EXPERTS WEIGH IN
“Psychogenic seizures are very common,” said Dr. French. “These findings suggest that people were able to self-monitor and they no longer needed to seek medical attention for what they thought were seizures. It is a positive outcome for a problem that we all see in our practices.”

“This is a challenging diagnosis,” added Gregory Kent Bergey, MD, a professor of neurology and director of the Johns Hopkins Epilepsy Center and vice chair for research in the department of neurology at Johns Hopkins. Dr. Bergey said that many patients with PNES have depression, anxiety or a mood disorder “They are not malingerers. They suffer from subconscious stressors.”

He said that it would be helpful if neurologists could arrive at the diagnosis earlier. “Generally, patients describe what sounds like a seizure and a physician will put them on an anti-seizure medication. If that doesn’t work, they’ll move on to prescribe another medication and then another if that doesn’t work. I suspect that an earlier appreciation of the fact that seizure medication is not working would help in the earlier recognition. The only way to diagnose psychogenic seizures is to send the patient in for continuous video EEG monitoring.”

Selm R. Benbadis, MD, professor and director of the Comprehensive Epilepsy Program University of South Florida and Tampa General Hospital, became interested in PNES as a fellow working at an epilepsy referral center. “It was so common and so neglected, especially by the mental health community,” said Dr. Benbadis. “It is very hard to find psychiatrists or psychologists interested in the issue, or who believe in the diagnosis. Patients are literally caught in the middle.”

PNES is not different than other conversion disorders but neurologists actually have a tool that can rule out epilepsy: EEG video monitoring. “PNES is a relatively easy diagnosis to make once we look at the EEG and the video tapes,” said Dr. Benbadis.

“If you explain it to patients carefully and compassionately they do understand. The real problem comes from finding mental health professionals to deliver treatments.” He said that studies have shown that selective serotonin reuptake inhibitors work, as does cognitive behavioral therapy.

TUNE IN: Investigators pored through eight years of medical records — seven years before the diagnosis of psychogenic nonepileptic seizures (PNES) was made and one year after — and found that the patients’ use of hospitals and clinics decreased dramatically after they were given the proper diagnosis. Watch here as Neurology Today editorial advisory board member Jacqueline A. French, MD, professor of neurology at New York University Comprehensive Epilepsy Center and president of the American Epilepsy Society, discusses what this can mean for clinicians seeing patients with PNES: http://bit.ly/Xg56E5.

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ARTICLE IN BRIEF
Policy experts discuss the effect the sequestration will have on Medicare reimbursement for neurologists and offer some potential coding strategies to mitigate potential losses in revenue.

Former AAN President Bruce Sigsbee, MD, voiced concern that the cuts are tough to absorb amid ever-rising overhead expenses. A neurology practice typically has a 60-percent overhead, which pays for salaries, benefits, and malpractice insurance. Other nonprocedure specialties — such as primary care, infectious diseases, endocrinology, and rheumatology — have similar overhead percentages.

A 2-percent reimbursement reduction typically leads to a 5-percent decrease in take-home pay. A 7-percent cut translates into an 18-percent drop in take-home pay for the average practice, creating a dire situation, according to Dr. Sigsbee, who practices at Pen Bay Physicians & Associates in Rockport, ME.

“We are employed by a hospital and there’s some buffer,” he said of his multi-specialty 60-physicians group, which includes four neurologists. Salary is based in part on productivity, not actual reimbursement. This arrangement has been in place for about four years, and Dr. Sigsbee expects some changes.

Dr. Benbadis wrote an editorial on the topic in February in the journal, Neuropsychiatry, in which he points out the lack of involvement of the professional mental health organizations. “Outcome and follow-up are notoriously poor for this patient population. For PNES, a common scenario is that patients are caught going back and forth between psychiatry and neurology.”
“but we still will be at a higher salary level than if we were an independent private practice.”

Nonetheless, “neurologic practices including the whole spectrum — from solo private practice to groups to academic medical centers — are really struggling at this point,” he said. “And I don’t think there are any easy solutions to all of these issues.”

Dr. Sigsbee, who began practicing neurology in 1980 after completing his residency training, said he has encountered neurologists who are closing their practices because it has become unaffordable to keep the doors open. “There’s no question that this is the hardest time that neurology has ever seen,” said Dr. Sigsbee.

Former AAN Medical Economics and Management (MEM) Committee Chair Marc R. Nuwer, MD, PhD, professor of neurology at the University of California, Los Angeles David Geffen School of Medicine, said he also knows neurologists who are retiring early. For some, the 2-percent Medicare reduction for office visits “might be the straw that breaks the camel’s back,” but this alone won’t cause a “mass exodus” of neurologists.

“It is one thing after another after another” that forces physicians out of the profession, said Dr. Nuwer. “This is all cumulative. This is one of many cuts, it is death by a thousand cuts.”

STRATEGIES TO MITIGATE LOSSES

The AAN proposes a few strategies to help neurology practices mitigate potential losses. One way to spur additional revenue is to use two new Current Procedural Terminology (CPT) codes for Transitional Care Management (TCM) services — those activities neurologists and their support staff perform to help manage a patient’s transition from an inpatient hospital setting, partial hospitalization, observation status or skilled nursing facility to their home, nursing home, or assisted living facility.

The activities can include a combination of at least one face-to-face visit and non-face-to-face services, such as telephone and electronic communications with the patient and/or caregiver within two business days of discharge by the physician or qualified and licensed clinical staff who report to him or her. [See page 12 in the April edition of the AAN-news for more details about the TCM codes: http://bit.ly/YOaiWO]

Asked about the new codes, Amy Kaloides, AAN director of advocacy, said in an e-mail that the main takeaway message for neurologists is that “CMS is now reimbursing physicians for work that was largely already being performed. Additionally this sets an exciting precedent for Medicare to reimburse for non-face-to-face activities.”

A second AAN recommendation involves delegating some tasks to physician assistants and nurse practitioners. Thirdly, the AAN suggests properly documenting adherence to quality measures in disease.
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management this year as part of the CMS Physician Quality Reporting System (PQRS). Neurologists who successfully report to PQRS will receive a 0.5 percent bonus on their Medicare claims each year through 2014; but beginning in 2015 — and based on 2013 FY reporting — those who do not report will see a 1.5 percent penalty that grows to 2 percent in 2016.

Meanwhile, Kaloides said, on the advocacy front, “We’re continuing to press Congress to come together to find a resolution and prevent sequestration cuts from happening in subsequent fiscal years.”

Bill Henderson, administrator of The Neurology Group in Albany, NY, said the eight-physician practice made internal adjustments to lower expenses in anticipation of declining Medicare reimbursement, which was projected to put a 9-percent dent in its revenue. “When we did our budgeting for 2013, we already planned that the sequester would go into effect,” said Henderson, a member of the AAN MEM Committee.

As a result, the neurology group no longer pays 100 percent of the health insurance premium for single-coverage employees. Those workers are now required to contribute 25 percent toward the premium. The group also made changes to its retirement plan and is eliminating a couple of full-time office positions. “In every practice, you’re looking for work efficiencies, and in one case, we had an office with one too many staff members,” said Henderson.

Aside from the eight neurologists, the practice employs a total of about 35 nurse practitioners, physician assistants, nurses, medical assistants, office and internal billing staff. The group operates three offices in counties around Albany, and there are currently no plans for consolidation.

Other operating strategies call for “alternative revenue streams that will add additional income into the practice,” said Henderson. This means exploring ways to schedule patients’ appointments that allow for more seamless management of physicians’ work flow. The practice also has become firmer in enforcing a $35 no-show fee for patients who miss their booked appointments.

One of the challenges in providing neurologic care is meeting the time required to handle complex problems under shrinking revenues, along with practicing cost-efficient care. A neurologist can easily spend 30 minutes interacting with a new patient who suffers from migraines or with the family of a patient who has Alzheimer’s disease, said Dr. Jones.

“Someone coming in with headaches is always convinced they have a brain tumor,” she said. It’s her role as a neurologist to explain why an expensive test may not be necessary. “You’re trying your best to save money and not do an MRI on every patient who comes in with a headache.”

The satisfaction that comes from taking care of patients is what motivated Dr. Jones to pursue a career in health care. “I like explaining things,” she said. “I don’t want to just see someone and write a prescription. That’s not why I went into this.”

As she spends more time immersed in paperwork and prior authorizations, it becomes increasingly difficult to devote as much time to her patients as she wants to do. “I love teaching them about neurology and their disease specifically,” said Dr. Jones. “That’s time-intensive.”

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